



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,043	02/17/2004	William H. Fleming	6122-67949-01	8393
24197	7590	12/14/2006	EXAMINER	
KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204			STEPHENS, JACQUELINE F	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/781,043

Applicant(s)

FLEMING, WILLIAM H.

Examiner

Jacqueline F. Stephens

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-43 is/are rejected.  
7) ☒ Claim(s) 44-48 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/2/06  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive. In response to applicant's argument that Hirschman does not disclose a pad that absorbs anal leakage, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Hirschmann discloses it absorbs bodily discharge (Abstract), therefore, it is also capable of absorbing anal leakage. If the prior art structure is capable of performing the intended use, then it meets the claim limitations.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1- 6, 10-15, 18, 20, 21, 24-28, 31-41, and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschman USPN 3983873.

As to claims 1, 2, 5, 10-12, 13-15, 18, 21, 24-28, 31, and 49-50, Hirschman discloses an interlabial device comprising a pad, wherein the pad is configured to be

Art Unit: 3761

retained between labia of a subject and the pad (Abstract). Hirschman discloses the pad is self-retained (col. 3, lines 7-10), which indicates no adhesive is used to retain the pad. The pad has a minor portion superimposed on a major portion, the minor portion having a cross-sectional area smaller than a cross-sectional area of the major portion (Figures 1-14). The minor portion is tapered to facilitate insertion between the labia and retention in the interlabial space (Abstract). Hirschman does not disclosed a method of using the pad for absorbing leakage from an anus or to treat hemorrhoids. However, the claimed novel structure of the pad is old and known from Hirschman. Since the claimed method also recites a method for using the structure, which is similar to Hirschman, it is within the level of one of ordinary skill in the art to use the pad for anal leakage. The pad is being used in the same manner to absorb leakage and is self-retained within the user. "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978)"; In re Tomlinson, 363 F.2d 928, 150 USPQ 623 (CCPA 1966).

Regarding the limitation of "a width, which is wider than a normal anatomic intergluteal space", applicant has not defined a normal anatomic intergluteal space, which obviously can vary depending on the user. The fact that the pad of Hirschman is self-retained in the user indicates it has sufficient width (in the posterior portion), which is wider than a 'normal' anatomic intergluteal space.

As to claim 3, Hirschman discloses the pad is a highly absorbent non-swellable material (Hirschman col. 2, lines 61-64).

As to claim 4 and 20, see Hirschman figures 1-14 and Hirschman Abstract.

As to claim 6, see Hirschman figures 13-15.

As to claims 32, 34-41, see Hirschman Figures 1-14.

As to claims 33, Hirschman discloses the pad is self-retained (col. 3, lines 7-10), which indicates no adhesive is used to retain the pad.

4. Claims 7, 8, 9, 19, 22, 23, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschman USPN 3983873 in view of Rosenbluth USPN 5074855

As to claims 8, 19, 22, and 42, Hirschman does not disclose the pad carries a therapeutically or diagnostically effective amount of a diagnostic or therapeutic agent. Rosenbluth discloses a pad, which carries a therapeutically or diagnostically effective amount of a diagnostic or therapeutic agent for the benefit of preventing drying of the wearer's tissue and to reduce friction of the structure against the wearer (Rosenbluth col. 2, lines 55-57 and col. 5, lines 7-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pad of

Hirschman to have a therapeutically or diagnostically effective amount of a diagnostic or therapeutic agent for the benefit of inhibiting infection. Because the pad comprises a medically-active compound, its use inherently requires selecting a person in need of a medically-active compound.

As to claim 7, see Rosenbluth col. 5, lines 7-11.

As to claims 9, 23, and 43 see Rosenbluth col. 2, lines 55-57 and col. 5, lines 7-11.

5. Claims 16, 17, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschman USPN 3983873 in view of Okuda et al. USPN 4920045. Hirschman does not disclose the step of performing a diagnostic test on the fecal material. Okuda discloses detection of occult blood in feces for the purpose of early finding an abnormality such as cancer or ulcer in digestion organs at an early stage (col. 4, lines 4-14). It would have been obvious to one having ordinary skill in the art to provide the step of diagnostic testing for the benefits disclosed in Okuda.

6. Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschman USPN 3983873 in view of Di Cintio et al. USPN 6967025. Hirschman does not disclose an odor control material in the pad. Di Cintio teaches interlabial pads comprising charcoal for the benefit of reducing undesirable odor (col.

15, line 45 through col. 16, line 25). It would have been obvious to one having ordinary skill in the art to provide the an odor control agent for the benefits disclosed in Di Cintio.

***Allowable Subject Matter***


7. Claim 44-48 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F. Stephens whose telephone number is (571) 272-4937. The examiner can normally be reached on Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jacqueline F Stephens  
Primary Examiner  
Art Unit 3761

December 11, 2006